DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2014

IsoAid, LLC
% Mary Ann Greenawalt
Regulatory & Quality Director
7824 Clark Moody Blvd.
PORT RICHEY FL 34668

Re: K141701
Trade/Device Name: I-125 Radioactive Seed And Localization Needle
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: October 29, 2014
Received: October 30, 2014

Dear Ms. Greenawalt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141701

Device Name

Radioactive Seed Localization Needle [RSLN]

Indications for Use *(Describe)*

The IsoAid RSLN is a device intended for the localization of suscipcious tissues (non-palpable lesions) for excision with the use of radioactive seeds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) SUMMARY

(As required by 807.92(c))

Submitter of 510(k): IsoAid, LLC
7824 Clark Moody Blvd., Port Richey, FL 34668
Phone: 727-815-3262
Fax: 727-815-1973

Contact Person: Mary Ann Greenawalt
IsoAid Regulatory and Quality

Date of Summary: 23 JUNE 2014

Trade Name: I-125 Radioactive Seed Localization Needle [IA-RSLN]

Common Name: Source, Brachytherapy, Radionuclide

Classification: Class II [21 CFR 892.5730, Product Code KXK]

Classification Name: Radionuclide Brachytherapy Source

Predicate Devices:

Device	510(k)
BrachySciences (Biocompatibles)Radioactive Seed Localization Needle with Anchor Seed	K111979

Device Description: The IsoAid I-125 Radioactive Seed Localization Needle [IA-RSLN] is a pre-sterilized 18 gauge needle containing a low-activity I-125 Iodine Seed [K011205]. The needle tip is occluded with bone wax to contain the contents prior to implant. The iodine seed is loaded loose or stranded and is provided with or without trailing spacers. The stainless steel needles are provided in lengths: 5cm, 7cm, and 12cm. The device is used to facilitate the introduction of the radionuclide seed into the suspicious tissue. The seed is used singly as a point-source for localization rather than for therapeutic use as in brachytherapy. The device is packaged and labeled and EtO sterilized.

Intended Use: The I-125 Radioactive Seed Localization Needle is intended as a temporary implant to aid in localization and excision of suspicious tissues It is intended to be used with or without absorbable strands.

Indications for Use: The I-125 Radioactive Seed Localization Needle is intended for the localization of suspicious tissues [non-palpable lesions] for excision with the use of radioactive seeds.

Summary of Technological Characteristics.
The IsoAid I-125 RSLN device has the same intended use and fundamental scientific technology as the predicate device. As with the predicate device, the I-125 RSLN device is an iodine radionuclide seed provided loose or stranded, with or without a trailing spacer. The RSLN device is provided sterile for one-time use only, and meets ISO 2919, ISO 9978, and Type A packaging requirements.

Conclusion.
Based on the above, IsoAid LLC believes the RSLN device is substantially equivalent to the predicate device, and is safe and effective for its intended use.

-end-

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